

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN**

TRUTEK CORP.,

Plaintiff/Counter-Defendant,

v.

BLUEWILLOW BIOLOGICS, INC.

Defendant/Counter-Plaintiff,

ROBIN ROE 1 through 10 (fictitious
names); ABC CORPORATION 1
through 10 (fictitious names),

Defendants.

Case No. 2:21-cv-10312

Hon. Stephen J. Murphy, III

Mag. R. Steven Whalen

**DEFENDANT BLUEWILLOW BIOLOGICS, INC.'S
RESPONSIVE CLAIM CONSTRUCTION BRIEF**

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Pursuant to the Order Setting Claim Construction (ECF 35), BlueWillow Biologics, Inc. (“BlueWillow”) submits its Responsive Brief to Plaintiff Trutek Corp.’s (“Trutek”) Opening Brief on Claim Construction Issues for Markman Hearing (ECF 37).

I. INTRODUCTION

Before addressing the substance of Trutek’s arguments, BlueWillow notes that Trutek makes misstatements regarding the law of claim construction.¹

First, for many terms, Trutek ignores the intrinsic record and, instead, cites only dictionary definitions. However, it is well-established precedent that extrinsic evidence, such as dictionary definitions, is “less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (*en banc*) (quoting *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004)). Indeed, the Federal Circuit has explained that: “[u]nless the inventor intended a term to cover more than the ordinary and customary meaning *revealed by the context of the intrinsic record*, it is improper to read the term to encompass a broader definition simply because it may be found in a dictionary, treatise, or other extrinsic source.”

¹ In the legal standard section of its brief, Trutek references means-plus function claiming (35 U.S.C. § 112(6)). However, neither party is asserting that any term should be given means-plus function treatment.

Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc., 711 F.3d 1348, 1362 (Fed. Cir. 2013) (citation omitted) (emphasis in original).

Second, Trutek improperly seeks to have the Court construe every term in the asserted claims. As explained in BlueWillow’s Opening Claim Construction Brief (ECF 38), the Federal Circuit has made clear that the Court is not required to “repeat or restate every claim term in order to comply with the ruling that claim construction is for the court.” *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997); *see also Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy”).

II. TRUTEK FAILS TO EXPLAIN HOW CERTAIN TERMS MEET THE DEFINITENESS REQUIREMENT

A. Trutek’s Failure to Proffer Expert Testimony Supports Finding the Claims Indefinite

In arguing that the claims meet the definiteness requirement of 35 U.S.C. § 112, Trutek fails to cite any expert testimony. The Federal Circuit has found that such failure supports finding the asserted claims indefinite. For example, in *Berkheimer v. HP, Inc.*, the Federal Circuit affirmed the district court’s holding that “the term ‘archive exhibits minimal redundancy’” was indefinite because “the intrinsic evidence leaves a person skilled in the art with a highly subjective meaning of minimal redundancy.” 881 F.3d 1360, 1363 (Fed. Cir. 2018). In doing

so, the Federal Circuit approved of the district court’s reliance on the unrebutted expert testimony proffered by the accused infringer that “the patent does not inform a skilled artisan of the meaning of ‘archive exhibits minimal redundancy’ with reasonable certainty.” *Id.* at 1364; *see also Icon Health & Fitness, Inc. v. Polar Electro Oy*, 656 F.App’x 1008, 1015 n.1 (Fed. Cir. 2016) (relying on “expert’s unrebutted analysis” in affirming finding of indefiniteness). Accordingly, Trutek’s failure to proffer expert testimony of its own further supports finding the asserted claims indefinite.

B. Trutek Fails to Explain How These Terms Meet the Definiteness Requirement

1. “electrostatically inhibiting” and “electrostatically attracting” (claims 1 & 2)

Trutek’s arguments regarding the meanings of “electrostatically inhibiting” and “electrostatically attracting” improperly assume that the definiteness requirement merely requires that a person of ordinary skill in the art (“POSA”) would be able to discern some meaning as to a particular term to find the term is definite. Trutek argues that “electrostatically inhibiting” means “using an electrostatic field to attract or repel harmful particles” and “electrostatically attracting” means that “once applied, the formulation exhibits a static charge, while the ‘harmful particles’ exhibit an opposite charge.” (ECF 37, Trutek Opening Br., PgID 546.)

However, the U.S. Supreme Court has explicitly held that the definiteness requirement requires more than simply that a term be “amenable to construction.” Prior to *Nautilus, Inc. v. Biosig Instruments, Inc.*, Federal Circuit precedent as to indefiniteness required courts to evaluate whether “claims were ‘amenable to construction’ or ‘insolubly ambiguous.’” 572 U.S. 898, 912 (U.S. 2014). In rejecting this standard, the Court explained that “[i]t cannot be sufficient that a court can ascribe some meaning to a patent’s claims.” *Id.* Rather, the proper standard to apply in indefiniteness inquiries is whether “a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art ***about the scope of the invention with reasonable certainty.***” *Id.* at 910 (emphasis added).

Here, Trutek fails to articulate or explain how a POSA would understand the scope of “electrostatically inhibiting” and “electrostatically attracting” within the context of the asserted claims with reasonable certainty. Instead, as explained in BlueWillow’s Opening Brief and by Dr. Amiji, the ’802 Patent does not provide any information or guidance to a POSA to allow such person to assess with reasonable certainty the scope of potential formulations that are capable of achieving the claimed functions of “electrostatically inhibiting” and “electrostatically attracting” harmful particulate matter. (ECF 38, BlueWillow Opening Br., PgID 595–98.) Trutek’s inability to address this fundamental issue

regarding the scope of these terms highlights that the terms lack reasonable certainty.

More specifically, Trutek's explanation that "electrostatically inhibiting" means "using an electrostatic field to attract or repel harmful particles" does not inform a POSA as to any of the quantitative parameters of the electrostatic field, including what magnitude is necessary to attract or repel harmful particles, how far the field needs to be from the surface, or how long it must remain to be effective. (ECF 38-3, Amiji Decl., ¶ 36.) Similarly, Trutek's assertion that "electrostatically attracting" means that "once applied, the formulation exhibits a static charge, while the 'harmful particles' exhibit an opposite charge" also does not inform the POSA as to the quantitative boundaries necessary for the electric charge, particularly in view of the breadth of the claims and the potential formulations disclosed in the patent. (*Id.* ¶ 35 (explaining that the '802 Patent admits that varying the percentages of the formulation ingredients would impact the potency and consistency of the formulation, which in turn would impact the ability of the formulation to "electrostatically attract" and "electrostatically inhibit" harmful particulate matter).)

In addition, Trutek's explanation as to the meaning of the specific terms "electrostatically inhibiting" and "electrostatically attracting" is inconsistent with its own proposed constructions. (*See* ECF 37, Trutek Opening Br., Ex. A (claim

chart with proposed constructions).) Notably, Trutek does not seek to construe either of these specific claim terms, arguing instead for a “construction” of the entire limitation containing these specific terms. For example, the term “electrostatically inhibiting” is found in the preamble of claims 1 and 2. While Trutek explains in its Opening Brief that this term means “using an electrostatic field to attract or repel harmful particles,” (*id.* at PgID 599), its proposed construction of the claim preamble does not even use the phrases “electrostatic field” or “attract or repel,” referring instead to “preventing an individual from becoming infected” through a formulation that exhibits a “static electrical charge,” (*id.* at Ex. A).

Moreover, that the examiner suggested using the word “inhibiting” does not preclude a finding of indefiniteness. In suggesting this language, the examiner was evaluating the claims in the context of enablement²—an “analytically distinct requirement” from indefiniteness. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 n.2 (Fed. Cir. 1999). Indeed, it is also worth noting the examiner was evaluating the claims prior to the U.S. Supreme Court’s seminal ruling in *Nautilus*.

² (ECF 38-4, Office Action, 2).)

2. **“adequate impermeability” (claims 1 & 2)**

Trutek’s arguments regarding “adequate impermeability” likewise fail to identify any standard that would inform a POSA as to how to determine what amount of impermeability is adequate. Trutek argues that “adequate impermeability” “refers to thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual’s nasal passages.” (ECF 37, Trutek Opening Br., PgID 562 (emphasis in original).) However, such a definition does not answer the salient question, i.e., how impermeable must the thin film be.

As an initial matter, the term “adequate impermeability” is found in element b) of claims 1 and 2 of the ’802 Patent. Again, Trutek does not offer a proposed construction for this claim term, choosing instead to offer a proposed construction of the entire limitation containing the term. (ECF 37, Trutek Opening Br., Ex. A.) Notably, Trutek’s proposed construction simply uses the phrase “impermeability” and again, is inconsistent with the explanation Trutek provided in its Opening Brief as to the meaning of “adequate impermeability.” (*Id.* at 18.) Trutek’s proposed construction of the claim limitation says nothing about “inhibiting harmful particles from penetrating the thin film and contacting the skin or tissue.” (*Id.* at Ex. A.)

In addition, despite acknowledging that because “adequate impermeability” “uses a term of degree (i.e., adequate),” the specification must “provide[] some standard for measuring that degree,” Trutek fails to identify any such standard in the ’802 Patent. Instead, Trutek points to the “ten examples (Tables 1 - 10) of formulations that all function as in the claims.” (ECF 37, Trutek Opening Br., PgId 563.) Trutek argues that such formulations merely “contain ingredient compositions the concentration of which is given in ranges” and that “the actual ingredient concentrations need to be adjusted by one having ordinary skill in the art (i.e., a formulator) to have the *desired characteristics of adhesion of the thin film along with its tackiness to capture and hold the harmful particles*, thus providing adequate impermeability.” (*Id.* at PgID 563–64 (emphasis added).)

However, Trutek does not identify any objective guidance or criteria provided in the ’802 Patent as to what level of adhesion is necessary to adequately “capture and hold the harmful particles.” Instead, as explained in BlueWillow’s Opening Brief, a POSA would not be able to assess with reasonable certainty whether any potential formulations fall within the subjective bounds of providing “adequate permeability” to the thin film. (ECF 38, BlueWillow Opening Br., PgID 598–99; ECF 38-3, Amiji Decl., ¶ 37.) This is particularly noteworthy given that the ’802 Patent contains no examples, data or test results for any of the formulations demonstrating the level of adhesion or impermeability attained by

those formulations, while also conceding that “varying the percentages” of the ingredients affects both the potency and consistency of the formulation. (ECF 38-3, Amiji Decl., ¶¶ 32–33, 35 (further explaining that the potency and consistency of the formulation will impact the properties of the formulation, including its level of impermeability).)

Moreover, in arguing that it would not take “undue experimentation” for a POSA to practice the asserted claims, Trutek, once again, improperly conflates the standard for indefiniteness with that of enablement. (ECF 37, Trutek Opening Br., PgID 564. Indefiniteness evaluates whether a POSA would be able to evaluate the scope of the claims with “reasonable certainty”—not the amount of experimentation it would take for a POSA to practice the claims.

3. **“render[s] said particulate matter harmless” (claims 1 & 2)**

Trutek argues that the term “refers to one or more microorganisms being captured, killed, and inactivated.” (ECF 37, Trutek Opening Br., PgID 562.) However, this argument fails to explain what is needed for the formulation to “render . . . particulate matter harmless.” Instead, as explained in BlueWillow’s Opening Brief, this a highly subjective inquiry that will depend on the specific particulate matter that is to be rendered harmless. (See ECF 38, BlueWillow Opening Br., PgID 600–601; Amiji Decl. at ¶ 38.)

In addition, Trutek’s explanation for what this claim term means is inconsistent with its construction for the claim limitation in which the term is found. The term “render[s] said particulate matter harmless” is found in element c) of claims 1 and 2. Trutek’s proposed construction for claim 1 element c) does not reference microorganisms or particulate matter being “captured,” and its construction refers to “killing *or* inactivating,” not “killing *and* inactivating.” Trutek’s own claim construction suggests that something can be rendered harmless by either killing or inactivating – two distinct concepts – not that it must be both killed and inactivated. Turning to claim 2, Trutek proposes that the exact same claim language (“render[s] said particulate matter harmless”) simply means “inactivates the captured harmful particles,” and says nothing about the particulate matter being “killed.”

Each of these inconsistencies between Trutek’s proposed claim constructions and its argument as to the meaning of “render[s] said particulate matter harmless” further highlights that the term lacks reasonable certainty.

III. TRUTEK’S REMAINING CLAIM CONSTRUCTION POSITIONS SHOULD BE REJECTED

Trutek also offers constructions and interpretations for several other terms and each limitation of the asserted claims as a whole. (*See* ECF 37, Trutek Opening Br., ECF 545–57.) However, in doing so, it is unclear if Trutek is asking

for construction of the eleven terms addressed at pages 14-19 of its Opening Brief³, or if it is proposing that each of the claim limitations be construed in their entirety according to the “Interpretation” provided in Exhibit A.⁴ In either scenario, Trutek has not explained why there is a need for any of the proposed constructions as opposed to applying the plain and ordinary meaning of the claim terms and thus, needlessly seeks to have the Court engage in an unnecessary exercise in redundancy.

For example, Trutek proposes construing “electrostatically” as “static electricity” that “utilize[es] electrically charged particles.” *Id.* at 14. While BlueWillow does not necessarily disagree with Trutek’s understanding of “electrostatically,” “electrostatically” is a term that has a well understood meaning for which no construction is needed. *See Graco Children’s Prods., Inc. v. Chicco USA, Inc.*, 548 F. Supp. 2d 195, 204 (E.D. Pa. 2008) (refusing to construe term where the plaintiff failed to explain that the construction was “necessary and would

³ For some of the eleven terms contained within pages 14-19 of Trutek’s Opening Brief, Trutek appears to provide a particular meaning (e.g., “electrostatically inhibiting”), although that meaning is different from what Trutek provided in Exhibit A. In other instances (e.g., “thin film”), Trutek merely provides a general discussion of the term without any proposed construction or citation to any intrinsic or extrinsic evidence.

⁴ During the parties’ meet and confer prior to filing their respective Opening Briefs, Trutek’s counsel stated that its proposed constructions were those contained in Exhibit A.

be more helpful to a juror than the plain language of the term itself”). Likewise, Trutek cites a number of dictionary definitions for many of the terms, without explaining why such extrinsic evidence is necessary to define any of the claim terms in view of the intrinsic record or their plain and ordinary meaning.

There are also a number of irreconcilable flaws contained within Trutek’s “Interpretations” in Exhibit A. Each should be rejected and the plain and ordinary meaning should govern (to the extent the claims are not found indefinite).

For example, Trutek’s Interpretation of the preambles of claims 1 and 2 refers to the concept of “preventing an individual from becoming infected” (or “prevents that person from being infected”). During prosecution, the examiner rejected use of the term “preventing” and required Trutek to amend the claims to “inhibiting.” (ECF 38-4 at 2); *Ajinomoto Co., Inc. v. Int’l Trade Comm’n*, 932 F.3d 1342, 1351 (Fed. Cir. 2019) (“when a word is changed during prosecution, the change tends to suggest that the new word differs in meaning in some way from the original word”). Trutek’s proposed constructions for the preambles are also improper for the additional reason that they read out the requirement of “electrostatically inhibiting harmful particulate matter from infecting an individual,” for the reasons explained in BlueWillow’s Opening Brief. *See Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 29 (1997) (“[e]ach element contained in a patent claim is deemed material to defining the

scope of the patented invention”); *Verizon Servs. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1308 (Fed. Cir. 2007) (“[w]hen a patent . . . describes the features of the ‘present invention’ as a whole, this description limits the scope of the invention”).

With respect to claim 2 element a), the plain language of the claim refers to “electrostatically attracting the particulate matter to the thin film.” There is no reason to add the additional explanation proposed by Trutek in Exhibit A that the cationic agent is positively charged and “most harmful particles are negatively charged.” *See Intervet America, Inc. v. Kee-Vet Laboratories, Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) (“[T]his court has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention, that limitations appearing in the specification will not be read into claims, and that interpreting what is meant by a word in a claim is not to be confused with adding an extraneous limitation appearing in the specification, which is improper.”) (citations omitted). Nor has Trutek provided any support – intrinsic or extrinsic – for the assertion that “most harmful particles are negatively charged.” Further, the language of element a) in claims 1 and 2 is nearly identical, with the only difference being the tense for the terms “attracting” and “attracts.” Nevertheless, Trutek offers two different proposed constructions for this claim element in Exhibit A, and provides no explanation for why this is necessary or appropriate in view of

the intrinsic record. *See Paragon Solutions, LLC v. Timex Corp.*, 566 F.3d 1075, 1087 (Fed. Cir. 2009) (“We apply a presumption that the same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims.”) (citations omitted).

Trutek’s proposed “Interpretation” for element b) of claims 1 and 2 is likewise flawed. The plain language of the claims recites “adequately impermeability,” whereas Trutek’s proposed “Interpretation” eliminates the word “adequately,” referring only to the thin film being “impermeable.” *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) (“claims are interpreted with an eye toward giving effect to all terms in the claim”).

Finally, there are a number of issues with Trutek’s proposed Interpretation of element c) of claims 1 and 2, demonstrating why these constructions are improper as well. First, the language of claims 1 and 2 is very similar, with both claims requiring “inactivating/inactivates the particulate matter” and “render[s] said particulate matter harmless.” However, claim 1 recites the additional element of “adding at least one ingredient” to render the particulate matter harmless, whereas claim 2 does not specify how the particulate matter is rendered harmless. Despite this difference in claim language, Trutek’s proposed construction for element c) of claim 2 inserts the requirement that the “biocide in the formulation

inactivates the captured harmful particles and renders them harmless.” This is contrary to the plain language of claim 2, which simply requires that the particulate matter be rendered harmless. Nowhere does the plain language of claim 2 require the particulate matter to be rendered harmless *by the biocidic agent*. As such, Trutek’s proposed construction is improper. *See Anchor Wall Systems, Inc. v. Rockwood Retaining Walls, Inc.*, 340 F.3d 1298, 1306 (Fed. Cir. 2003) (“Notwithstanding the fact that the claim language must be examined in light of the written description, limitations may not be read into the claims from the written description”).

Trutek’s proposed Interpretation for element c) of claims 1 and 2 is also improper for the additional reason that the proposed meanings are different, despite nearly identical claim language. *See Paragon Solutions*, 566 F.3d at 1087. More specifically, despite the identical language of “inactivating/inactivates” and “render[s] said particulate matter harmless” in claims 1 and 2, Trutek’s proposed constructions for these nearly identical claim limitations are different. The proposed construction for claim 1 refers to rendering the particulate matter harmless “by killing or inactivating,” whereas the proposed construction for claim 2 merely refers to rendering the particulate matter harmless by “inactivat[ing],” and not by “killing.”

In summary, there is no reason for the Court to adopt Trutek's proposed constructions for any of the claim terms or limitations identified by Trutek. In many instances, Trutek has not identified or proposed any special meaning for these claim terms, and their plain and ordinary meaning should apply (to the extent the claim terms noted above are not found to be indefinite). *See Graco Children's Products*, 548 F. Supp.2d at 204. In other instances, Trutek proposes different constructions for nearly identical claim language in claims 1 and 2, without explaining why different interpretations are justified by the intrinsic record. In yet other instances, Trutek proposes constructions that are inconsistent with the intrinsic record, including the plain language of the claims and the prosecution history of the '802 Patent. Trutek's proposed constructions are improper for all of the foregoing reasons and should be rejected.

IV. CONCLUSION

For the reasons set forth above and in its Opening Brief, the Court should find each of the asserted claims 1, 2, 6 and 7 invalid as indefinite under 35 U.S.C. § 112, ¶ 2. In the alternative, if the claim terms are found to be sufficiently definite, the Court should construe the claim preambles as limiting and order that all of the claim terms be given their plain and ordinary meaning.

Dated: September 27, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2022, I electronically filed the foregoing document and accompanying exhibits with the Clerk of the Court for the Eastern District of Michigan using the ECF System, which will send electronic notice to all participants.

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